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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R.

To support endemic orphan fungal disease research, incentivize Valley Fever vaccine development, discover new antifungal therapies and diagnostics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCCARTHY introduced the following bill; which was referred to the Committee on _____

A BILL

To support endemic orphan fungal disease research, incentivize Valley Fever vaccine development, discover new antifungal therapies and diagnostics, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) IN GENERAL.—This Act may be cited as the
5 “Finding Orphan-disease Remedies With Antifungal Re-
6 search and Development Act of 2018” or the “FOR-
7 WARD Act of 2018”.

1 (b) TABLE OF CONTENTS.—The table of contents for
2 this Act is as follows:

- 3 Sec. 1. Short title; table of contents.
- 4 Sec. 2. Findings.
- 5 Sec. 3. Continuing support for research on endemic orphan fungal diseases.
- 6 Sec. 4. Endemic orphan fungal disease Federal-State match pilot program.
- 7 Sec. 5. FDA guidance for industry on development of diagnostics and
8 antifungal drugs and vaccines for Valley Fever.
- 9 Sec. 6. Including antifungal biological products as qualified infectious disease
10 products.
- 11 Sec. 7. Priority review to encourage treatments for endemic orphan fungal dis-
12 eases.
- 13 Sec. 8. Including antifungal products in the CARB-X program.
- 14 Sec. 9. Blockchain pilot program for hospital data security for coccidioidomy-
15 cosis research.

16 **SEC. 2. FINDINGS.**

17 Congress finds the following:

18 (1) Worldwide fungal infections, such as
19 candidiasis, cryptococcosis, and aspergillosis, often
pose fatal opportunistic threats to immunologically
impaired persons.

(2) Endemic fungal infections, such as
histoplasmosis, coccidioidomycosis, and blasto-
mycosis, occur in certain geographic regions world-
wide, including in the United States, and are ac-
quired through exposure to the environment.

(3) Because the endemic mycoses referred to in
paragraph (2) are regional, such endemic mycoses
do not receive the same amount of resources as
mycoses of worldwide distribution, even though with-
in the regions in which they are endemic such
strains pose significant public health threats.

1 (4) Coccidioidomycosis, also known as Valley
2 Fever, is a fungal infection acquired by the inhala-
3 tion of spores of certain fungi primarily found in the
4 soil endemic to the American Southwest, including
5 in Arizona, California, Nevada, New Mexico, Texas,
6 Utah, and Washington.

7 (5) According to the Morbidity and Mortality
8 Weekly Report issued by the Centers for Disease
9 Control and Prevention and dated August 11,
10 2017—

11 (A) 97 percent of the all reported cases of
12 Valley Fever occurred in California and Ari-
13 zona;

14 (B) individuals at increased risk for severe
15 Valley Fever include persons of African or Fili-
16 pino descent, pregnant women, adults in older
17 age groups, and other individuals with weak-
18 ened immune systems;

19 (C) the overall incident rate of Valley
20 Fever peaked in 2011 and again in 2016;

21 (D) in California, the Valley Fever incident
22 rate for 2016 was the highest recorded to date,
23 with 42 percent of cases reported coming from
24 Kern County; and

1 (E) the reason for increases in Valley
2 Fever cases reported in California in 2016 is
3 not known.

4 (6) Valley Fever illness ranges from influenza-
5 like symptoms to life-threatening when the infection
6 spreads to other parts of the body, including the
7 brain.

8 (7) The overall estimated impact of Valley
9 Fever is less than 200,000 people in the United
10 States, with roughly 200 deaths each year and over
11 11,000 new cases identified in 2016. The estimated
12 economic impact to the United States is at least
13 \$500,000,000 from hospital, outpatient, and lost
14 productivity costs.

15 (8) In the past 60 years, only 4 classes of
16 antifungal compounds have been approved by the
17 Food and Drug Administration for treatment for all
18 fungal infections.

19 (9) Existing antifungal therapies often do not
20 cure the fungal infection involved because, similar to
21 how bacteria have become resistant to antibiotic
22 therapies, some fungi no longer respond to the cur-
23 rent limited antifungal therapies that are designed
24 to treat them.

1 (10) *Coccidioides*, the cause of Valley Fever, is
2 not cured by any available drug.

3 (11) Although antibiotic-resistant bacterial in-
4 fections are a widely recognized public health threat,
5 less is known about the effects of antifungal resist-
6 ance and the burden of drug-resistant fungal infec-
7 tions.

8 (12) Fungal infections are a rising threat to
9 public health and the resistance to current
10 antifungal therapies will only complicate the Na-
11 tion's response in the event of a public health emer-
12 gency.

13 **SEC. 3. CONTINUING SUPPORT FOR RESEARCH ON EN-**
14 **DEMIC ORPHAN FUNGAL DISEASES.**

15 (a) IN GENERAL.—Subtitle F of title II of the 21st
16 Century Cures Act (Public Law 114–255) is amended by
17 inserting after section 2062 (42 U.S.C. 284s) the fol-
18 lowing new section:

19 **“SEC. 2062A. ENDEMIC ORPHAN FUNGAL DISEASES.**

20 “(a) IN GENERAL.—The Secretary of Health and
21 Human Services (in this section referred to as the ‘Sec-
22 retary’) shall continue to conduct or support epidemiolog-
23 ical, basic, translational, and clinical research related to
24 endemic orphan fungal diseases, including coccidioidomy-

1 cosis (commonly known as and referred to in this section
2 as ‘Valley Fever’).

3 “(b) REPORTS.—The Secretary shall ensure that
4 each triennial report under section 403 of the Public
5 Health Service Act (42 U.S.C. 283) includes information
6 on actions undertaken by the National Institutes of
7 Health to carry out subsection (a) with respect to endemic
8 orphan fungal diseases, including Valley Fever.

9 “(c) VALLEY FEVER WORKING GROUP.—

10 “(1) ESTABLISHMENT.—The Secretary shall es-
11 tablish a working group, to be known as the Valley
12 Fever Working Group (referred to in this section as
13 the ‘Working Group’), comprised of representatives
14 of appropriate Federal agencies and other non-Fed-
15 eral entities, to provide expertise and to review all
16 efforts within the Department of Health and Human
17 Services related to Valley Fever, to help ensure
18 interagency coordination and minimize overlap, and
19 to examine research priorities.

20 “(2) RESPONSIBILITIES.—The Working Group
21 shall—

22 “(A) not later than 2 years after the date
23 of enactment of this Act, develop or update a
24 summary of—

1 “(i) ongoing Valley Fever research, in-
2 cluding research related to causes, preven-
3 tion, treatment, surveillance, diagnosis,
4 diagnostics, duration of illness, and inter-
5 vention for individuals with Valley Fever;

6 “(ii) advances made pursuant to such
7 research;

8 “(iii) Federal activities related to Val-
9 ley Fever, including—

10 “(I) epidemiological activities re-
11 lated to Valley Fever; and

12 “(II) basic, clinical, and
13 translational Valley Fever research re-
14 lated to the pathogenesis, prevention,
15 diagnosis, and treatment of Valley
16 Fever;

17 “(iv) gaps in Valley Fever research
18 described in clause (iii)(II);

19 “(v) the Working Group’s meetings
20 required under paragraph (4); and

21 “(vi) the comments received by the
22 Working Group;

23 “(B) make recommendations to the Sec-
24 retary regarding any appropriate changes or

1 improvements to such activities and research;
2 and

3 “(C) solicit input from States, localities,
4 and nongovernmental entities, including organi-
5 zations representing patients, health care pro-
6 viders, researchers, and industry regarding sci-
7 entific advances, research questions, and sur-
8 veillance activities.

9 “(3) MEMBERSHIP.—The members of the
10 Working Group shall represent a diversity of sci-
11 entific disciplines and views and shall be composed
12 of the following members:

13 “(A) FEDERAL MEMBERS.—Seven Federal
14 members, consisting of one or more representa-
15 tives of each of the following:

16 “(i) The Office of the Assistant Sec-
17 retary for Health.

18 “(ii) The Food and Drug Administra-
19 tion.

20 “(iii) The Centers for Disease Control
21 and Prevention.

22 “(iv) The National Institutes of
23 Health.

24 “(v) Such other agencies and offices
25 of the Department of Health and Human

1 Services as the Secretary determines ap-
2 propriate.

3 “(B) NON-FEDERAL PUBLIC MEMBERS.—
4 Seven non-Federal public members, consisting
5 of representatives of the following categories:

6 “(i) Physicians and other medical pro-
7 viders with experience in diagnosing and
8 treating Valley Fever.

9 “(ii) Scientists or researchers with ex-
10 pertise.

11 “(iii) Patients and their family mem-
12 bers.

13 “(iv) Nonprofit organizations that ad-
14 vocate for patients with respect to Valley
15 Fever.

16 “(v) Other individuals whose expertise
17 is determined by the Secretary to be bene-
18 ficial to the functioning of the Working
19 Group.

20 “(4) MEETINGS.—The Working Group shall
21 meet annually.

22 “(5) REPORTING.—Not later than 2 years after
23 the date of enactment of this Act, and every 2 years
24 thereafter until termination of the Working Group

1 pursuant to paragraph (7), the Working Group
2 shall—

3 “(A) submit a report on its activities under
4 paragraph (2)(A) and any recommendations
5 under paragraph (2)(B) to the Secretary, the
6 Committee on Energy and Commerce of the
7 House of Representatives, and the Committee
8 on Health, Education, Labor, and Pensions of
9 the Senate; and

10 “(B) make such report publicly available
11 on the internet website of the Department of
12 Health and Human Services.

13 “(6) APPLICABILITY OF FACCA.—The Working
14 Group shall be treated as an advisory committee
15 subject to the Federal Advisory Committee Act (5
16 U.S.C. App.).

17 “(7) SUNSET.—The Working Group under this
18 section shall terminate 5 years after the date of en-
19 actment of this Act.

20 “(d) ENDEMIC ORPHAN FUNGAL DISEASE DE-
21 FINED.—The term ‘endemic orphan fungal disease’ has
22 the meaning given such term in section 529B(a) of the
23 Federal Food, Drug, and Cosmetic Act.”.

24 (b) CONFORMING TABLE OF CONTENTS AMEND-
25 MENT.—Section 1(b) of the 21st Century Cures Act (Pub-

1 lie Law 114–255) is amended in the table of contents, by
2 inserting after the item relating to section 2062 the fol-
3 lowing:

“Sec. 2062A. Endemic orphan fungal diseases.”.

4 **SEC. 4. ENDEMIC ORPHAN FUNGAL DISEASE FEDERAL-**
5 **STATE MATCH PILOT PROGRAM.**

6 (a) IN GENERAL.—For each of fiscal years 2019
7 through 2024, the Secretary of Health and Human Serv-
8 ices shall, subject to the availability of appropriations,
9 award grants through a competitive process to eligible en-
10 titities to conduct research with respect to endemic orphan
11 fungal diseases, including coccidioidomycosis.

12 (b) ELIGIBILITY.—An entity eligible to receive a
13 grant under this section is a State or local public hospital,
14 an institution of higher education (as defined in section
15 101 of the Higher Education Act of 1965 (20 U.S.C.
16 1001), or a nonprofit organization that has been provided
17 funds from State or local government sources for epide-
18 miological, basic, translational, and clinical research on
19 endemic orphan fungal diseases during the 3-year period
20 ending on the date of the enactment of this Act.

21 (c) APPLICATION.—An entity seeking a grant under
22 this section shall submit an application to the Secretary—
23 (1) in such form and manner as the Secretary
24 shall prescribe;

1 (2) that contains a certification that the entity
2 has received the funds described in subsection (b)
3 and that specifies the amount of such funds; and

4 (3) that contains such other information as the
5 Secretary may require.

6 (d) AMOUNT OF GRANT.—The amount of a grant
7 under this section shall equal (to the extent practicable)
8 the amount of funds received from State or local govern-
9 ment sources for the research that is the subject of the
10 grant.

11 (e) ENDEMIC ORPHAN FUNGAL DISEASE DE-
12 FINED.—The term “endemic orphan fungal disease” has
13 the meaning given such term in section 529B of the Fed-
14 eral Food, Drug, and Cosmetic Act, as added by section
15 7.

16 (f) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to carry out this section
18 \$8,000,000 for each of fiscal years 2019 through 2024,
19 to remain available until expended.

20 (g) SUNSET.—The Secretary may not award grants
21 under this section on or after October 1, 2024.

1 **SEC. 5. FDA GUIDANCE FOR INDUSTRY ON DEVELOPMENT**
2 **OF DIAGNOSTICS AND ANTIFUNGAL DRUGS**
3 **AND VACCINES FOR VALLEY FEVER.**

4 (a) **IN GENERAL.**—Not later than one year after the
5 date of the enactment of this Act, the Secretary of Health
6 and Human Services, acting through the Commissioner of
7 Food and Drugs, shall issue draft guidance for industry
8 for the purposes of assisting entities seeking approval
9 under the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 301 et seq.) or licensure under section 351 of the
11 Public Health Service Act (42 U.S.C. 262) of antifungal
12 therapies, diagnostics, or vaccines, specifically therapies,
13 diagnostics, and vaccines designed to diagnose, treat, or
14 prevent coccidioidomycosis (commonly known as Valley
15 Fever).

16 (b) **CONSULTATION.**—In developing the draft guid-
17 ance under subsection (a), the Secretary of Health and
18 Human Services, acting through the Commissioner of
19 Food and Drugs, shall consult with institutions of higher
20 education (as defined in section 101 of the Higher Edu-
21 cation Act of 1965 (20 U.S.C. 1001)), researchers, and
22 other relevant stakeholders.

23 (c) **FINAL GUIDANCE.**—The Secretary of Health and
24 Human Services, acting through the Commissioner of
25 Food and Drugs, shall finalize the draft guidance issued

1 under subsection (a) not later than 2 years after the date
2 of the enactment of this Act.

3 **SEC. 6. INCLUDING ANTIFUNGAL BIOLOGICAL PRODUCTS**
4 **AS QUALIFIED INFECTIOUS DISEASE PROD-**
5 **UCTS.**

6 (a) IN GENERAL.—Section 505E of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amend-
8 ed—

9 (1) in subsection (a)—

10 (A) by inserting “(or, pursuant to section
11 351 of the Public Health Service Act, in the
12 case of an antifungal biological product)” after
13 “pursuant to section 505 for a drug”; and

14 (B) by striking “or the 7-year period de-
15 scribed in section 527,” and inserting “the 7-
16 year period described in section 527, or, in the
17 case of an antifungal biological product, the 12-
18 year period under section 351(k) of the Public
19 Health Service Act,”;

20 (2) in subsection (c)—

21 (A) in paragraph (1), by inserting “or, in
22 the case of an antifungal biological product,
23 section 351(a) of the Public Health Service
24 Act” after “505(b)”; and

1 (B) in paragraph (2), by inserting “or, in
2 the case of an antifungal biological product,
3 section 351 of the Public Health Service Act”
4 after “505”;

5 (3) in subsection (d)(1) by inserting “or, in the
6 case of an antifungal biological product, section
7 351(a) of the Public Health Service Act” after
8 “505(b)”;

9 (4) in subsection (g), in the matter preceding
10 paragraph (1)—

11 (A) by inserting “(including antifungal bio-
12 logical products)” after “antifungal drug”; and

13 (B) by inserting “or prevent” after
14 “treat”.

15 (b) EFFECTIVE DATE.—The amendments made by
16 subsection (a) shall apply with respect to applications for
17 the approval of biological products under section 351 of
18 the Public Health Service Act (42 U.S.C. 262) submitted
19 on or after the date of the enactment of this Act.

20 (c) UPDATED GUIDANCE.—Not later than one year
21 after the date of the enactment of this Act, the Secretary
22 of Health and Human Services, acting through the Com-
23 missioner of Food and Drugs, shall update “Qualified In-
24 fectious Disease Product Designation Questions and An-

1 swers Guidance for Industry” issued in January 2018, to
2 implement the amendments made by subsection (a).

3 **SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
4 **FOR ENDEMIC ORPHAN FUNGAL DISEASES.**

5 Subchapter B of chapter V of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is
7 amended by adding at the end the following new section:

8 **“SEC. 529B. PRIORITY REVIEW TO ENCOURAGE TREAT-**
9 **MENTS FOR ENDEMIC ORPHAN FUNGAL DIS-**
10 **EASES.**

11 “(a) DEFINITIONS.—In this section:

12 “(1) ENDEMIC ORPHAN FUNGAL DISEASE.—
13 The term ‘endemic orphan fungal disease’ means a
14 disease, such as coccidioidomycosis, that—

15 “(A) is caused by a fungus;

16 “(B) primarily occurs in certain limited ge-
17 ographic regions; and

18 “(C) is a rare disease or condition (as that
19 term is defined in section 526(a)(2) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.
21 360bb(a)(2))).

22 “(2) ENDEMIC ORPHAN FUNGAL DISEASE DRUG
23 APPLICATION.—The term ‘endemic orphan fungal
24 disease drug application’ means an application
25 that—

1 “(A) is a human drug application for a
2 drug intended for use—

3 “(i) to prevent or treat harm from an
4 endemic orphan fungal disease; or

5 “(ii) to cure an endemic orphan
6 fungal disease;

7 “(B) the Secretary determines eligible for
8 priority review;

9 “(C) is approved after the date of enact-
10 ment of this section; and

11 “(D) is for a human drug, no active ingre-
12 dient (including any ester or salt of the active
13 ingredient) of which has been approved in any
14 other application under section 505(b)(1) or
15 section 351(a) of the Public Health Service Act.

16 “(3) HUMAN DRUG APPLICATION.—The term
17 ‘human drug application’ has the meaning given
18 such term in section 735(1).

19 “(4) PRIORITY REVIEW.—The term ‘priority re-
20 view’, with respect to a human drug application,
21 means review and action by the Secretary on such
22 application not later than 6 months after receipt by
23 the Secretary of such application, as described in the
24 Manual of Policies and Procedures in the Food and
25 Drug Administration and goals identified in the let-

1 ters described in section 101(b) of the Food and
2 Drug Administration Safety and Innovation Act.

3 “(5) PRIORITY REVIEW VOUCHER.—The term
4 ‘priority review voucher’ means a voucher issued by
5 the Secretary to the sponsor of an endemic orphan
6 fungal disease drug application that entitles the
7 holder of such voucher to priority review of a single
8 human drug application submitted under section
9 505(b)(1) or section 351(a) of the Public Health
10 Service Act after the date of approval of the endemic
11 orphan fungal disease drug application.

12 “(b) PRIORITY REVIEW VOUCHER.—

13 “(1) IN GENERAL.—The Secretary shall award
14 a priority review voucher to the sponsor of an en-
15 demic orphan fungal disease drug application upon
16 approval by the Secretary of such endemic orphan
17 fungal disease drug application.

18 “(2) TRANSFERABILITY.—The sponsor of a en-
19 demic orphan fungal disease drug application that
20 receives a priority review voucher under this section
21 may transfer (including by sale) the entitlement to
22 such voucher to a sponsor of a human drug for
23 which an application under section 505(b)(1) or sec-
24 tion 351(a) of the Public Health Service Act will be
25 submitted after the date of the approval of the en-

1 demic orphan fungal disease drug application. There
2 is no limit on the number of times a priority review
3 voucher may be transferred before such voucher is
4 used.

5 “(3) NOTIFICATION.—

6 “(A) IN GENERAL.—The sponsor of a
7 human drug application shall notify the Sec-
8 retary not later than 90 calendar days prior to
9 submission of the human drug application that
10 is the subject of a priority review voucher of an
11 intent to submit the human drug application,
12 including the date on which the sponsor intends
13 to submit the application. Such notification
14 shall be a legally binding commitment to pay
15 for the user fee to be assessed in accordance
16 with this section.

17 “(B) TRANSFER AFTER NOTICE.—The
18 sponsor of a human drug application that pro-
19 vides notification of the intent of such sponsor
20 to use the voucher for the human drug applica-
21 tion under subparagraph (A) may transfer the
22 voucher after such notification is provided, if
23 such sponsor has not yet submitted the human
24 drug application described in the notification.

25 “(c) PRIORITY REVIEW USER FEE.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a user fee program under which a sponsor of a
3 human drug application that is the subject of a pri-
4 ority review voucher shall pay to the Secretary a fee
5 determined under paragraph (2). Such fee shall be
6 in addition to any fee required to be submitted by
7 the sponsor under chapter VII.

8 “(2) FEE AMOUNT.—The amount of the pri-
9 ority review user fee shall be determined each fiscal
10 year by the Secretary and based on the average cost
11 incurred by the agency in the review of a human
12 drug application subject to priority review in the
13 previous fiscal year.

14 “(3) ANNUAL FEE SETTING.—The Secretary
15 shall establish, before the beginning of each fiscal
16 year beginning after September 30, 2019, for that
17 fiscal year, the amount of the priority review user
18 fee.

19 “(4) PAYMENT.—

20 “(A) IN GENERAL.—The priority review
21 user fee required by this subsection shall be due
22 upon the submission of a human drug applica-
23 tion under section 505(b)(1) or section 351(a)
24 of the Public Health Service Act for which the
25 priority review voucher is used.

1 “(B) COMPLETE APPLICATION.—An appli-
2 cation described under subparagraph (A) for
3 which the sponsor requests the use of a priority
4 review voucher shall be considered incomplete if
5 the fee required by this subsection and all other
6 applicable user fees are not paid in accordance
7 with the Secretary’s procedures for paying such
8 fees.

9 “(C) NO WAIVERS, EXEMPTIONS, REDUC-
10 TIONS, OR REFUNDS.—The Secretary may not
11 grant a waiver, exemption, reduction, or refund
12 of any fees due and payable under this section.

13 “(5) OFFSETTING COLLECTIONS.—Fees col-
14 lected pursuant to this subsection for any fiscal
15 year—

16 “(A) shall be deposited and credited as off-
17 setting collections to the account providing ap-
18 propriations to the Food and Drug Administra-
19 tion; and

20 “(B) shall not be collected for any fiscal
21 year except to the extent provided in advance in
22 appropriation Acts.

23 “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-
24 PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary
25 shall publish a notice in the Federal Register and on the

1 Internet website of the Food and Drug Administration not
2 later than 30 calendar days after the occurrence of each
3 of the following:

4 “(1) The Secretary issues a priority review
5 voucher under this section.

6 “(2) The Secretary approves a drug pursuant
7 to an application submitted under section 505(b) of
8 this Act or section 351(a) of the Public Health Serv-
9 ice Act for which the sponsor of the application used
10 a priority review voucher issued under this section.

11 “(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing
12 in this section precludes a sponsor who seeks a priority
13 review voucher under this section from participating in
14 any other incentive program, including under this Act, ex-
15 cept that no sponsor of a material threat medical counter-
16 measure application may receive more than one priority
17 review voucher issued under any section of this Act with
18 respect to such drug.

19 “(f) RELATION TO OTHER PROVISIONS.—The provi-
20 sions of this section shall supplement, not supplant, any
21 other provisions of this Act or the Public Health Service
22 Act that encourage the development of medical counter-
23 measures.

1 “(g) SUNSET.—The Secretary may not award any
2 priority review vouchers under subsection (b) after Octo-
3 ber 1, 2024.”.

4 **SEC. 8. INCLUDING ANTIFUNGAL PRODUCTS IN THE CARB-**
5 **X PROGRAM.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services shall, in carrying out the Combating An-
8 tibiotic Resistant Bacteria Accelerator program of the De-
9 partment of Health and Human Services (commonly re-
10 ferred to as “CARB-X”), conduct research with respect
11 to antifungal resistance, including therapies, diagnostics,
12 and vaccines, including for coccidioidomycosis.

13 (b) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated to the Biodefense Med-
15 ical Countermeasure Development Fund established under
16 section 319L(d) of the Public Health Service Act (42
17 U.S.C. 247d–7e(d)) to carry out subsection (a)
18 \$10,000,000 for each of fiscal years 2019 through 2024,
19 to remain available until expended.

20 **SEC. 9. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL**
21 **DATA SECURITY FOR COCCIDIOIDOMYCOSIS**
22 **RESEARCH.**

23 Part A of title IV of the Public Health Service Act
24 (42 U.S.C. 281 et seq.) is amended by adding at the end
25 the following new section:

1 **“SEC. 4040. BLOCKCHAIN PILOT PROGRAM FOR HOSPITAL**
2 **DATA SECURITY FOR COCCIDIOIDOMYCOSIS**
3 **RESEARCH.**

4 “(a) IN GENERAL.—The Director of NIH shall carry
5 out a pilot program to conduct, support, and facilitate
6 auditable research on coccidioidomycosis (commonly re-
7 ferred to as ‘Valley Fever’). In carrying out such program,
8 the Director shall—

9 “(1) award a grant to an eligible entity to in-
10 stall a blockchain on the servers of, or otherwise pro-
11 vide blockchain services to, the National Institutes of
12 Health, and provide support with respect to such a
13 blockchain, which shall contain public, unalterable
14 data which includes every query made through the
15 procedure established under subsection (c), as well
16 as the identity of the individual who asked such a
17 question, without disclosing the results of such que-
18 ries;

19 “(2) award a grant to an eligible entity—

20 “(A) to provide to not less than 3 qualified
21 hospitals qualified software; and

22 “(B) to provide customer service to each
23 such hospital with respect to such qualified
24 software or any associated service;

1 “(3) provide to such qualified hospitals any nec-
2 essary hardware in accordance with subsection (e);
3 and

4 “(4) award grants to eligible entities to test the
5 cybersecurity of such qualified hospitals by attempt-
6 ing to attack simulated data on the servers of such
7 hospitals.

8 “(b) ELIGIBLE ENTITIES; APPLICATION.—The Di-
9 rector of NIH shall determine whether an entity is eligible
10 to receive a grant under this section and shall select hos-
11 pitals to be qualified hospitals for purposes of this section.
12 An entity seeking a grant under this section, and a hos-
13 pital seeking to be so selected, shall submit to the Director
14 of NIH an application in such form and manner and con-
15 taining such information as the Director of NIH may
16 specify.

17 “(c) DATA QUERIES.—The Director of NIH shall es-
18 tablish, for purposes of allowing researchers to process
19 data from a qualified hospital’s servers pursuant to this
20 section, a procedure to determine—

21 “(1) who can ask queries of the servers;

22 “(2) which data the hospital must include on
23 such servers; and

1 “(3) which questions may be asked of such
2 servers, and what form of de-identification of the
3 servers’ data is required to ensure privacy.

4 “(d) REQUEST FOR PROPOSALS.—Not later than 90
5 days after the date of the enactment of this section, the
6 Director of NIH shall publish in the Federal Register a
7 request for proposals for grants under paragraphs (1), (2),
8 and (4) of subsection (a).

9 “(e) PROVISION OF SERVERS.—

10 “(1) IN GENERAL.—The Director of NIH shall,
11 in carrying out subsection (a)(3), provide to quali-
12 fied hospitals hardware, including computer servers,
13 sufficient to support qualified software.

14 “(2) CONDITION.—As a condition on the receipt
15 of a computer server under paragraph (1), a quali-
16 fied hospital shall agree not to use the qualified soft-
17 ware on the server to store data from patients of the
18 hospital until the Director of NIH determines that
19 testing performed pursuant to subsection (a)(4) has
20 determined that simulated data used in such soft-
21 ware could not be extracted from the hospital’s serv-
22 ers.

23 “(f) DEFINITIONS.—In this section:

24 “(1) The term ‘blockchain’ means software that
25 uses a distributed digital ledger of cryptographically

1 signed transactions that are grouped into blocks,
2 each of which—

3 “(A) is cryptographically linked to the pre-
4 vious block after validation and undergoing a
5 consensus decision; and

6 “(B) when added as a new block, makes
7 any older blocks more difficult to modify and is
8 replicated across all copies of the ledger within
9 the relevant network, with any conflicts in such
10 blocks resolved automatically using established
11 rules.

12 “(2) The term ‘qualified hospital’ means a hos-
13 pital that is located in a region in which coccidioi-
14 domycosis is endemic.

15 “(3) The term ‘qualified software’ means soft-
16 ware that uses secure multiparty encrypted com-
17 puting to allow researchers to perform computations
18 on encrypted data supplied by qualified hospitals.

19 “(4) The term ‘secure multiparty encrypted
20 computing’ means a form of cryptography in which
21 parties can jointly compute a function of inputs
22 while keeping those inputs private from each other,
23 and from all other parties, such as multiparty homo-
24 morphic encryption, threshold encryption, and secure
25 multiparty computation.

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 \$5,000,000 for fiscal year 2020, to remain available until
4 expended.”.